

08 CV 4183

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CASHIERS
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In Re: Fosamax Products Liability
Litigation:

MARIA COMBS, individually, and
ARDELL SMITH, individually,

Plaintiff,

vs.

MERCK & CO., INC., a New Jersey
corporation,

Defendant.

MDL No. 1789

CASE NO.

COMPLAINT

1. Strict Liability- Failure to Warn
2. Negligence
3. Breach of Implied Warranty
4. Breach of Express Warranty
5. Deceit by Concealment
6. Negligent Misrepresentation

DEMAND FOR JURY TRIAL

INTRODUCTION

This case involves the prescription drug Fosamax, which was manufactured, sold, distributed and promoted by Defendant Merck & Co., Inc. as a treatment for osteoporosis, Paget's Disease, and other conditions. Defendant misrepresented that Fosamax was a safe and effective treatment for these conditions, when in fact the drug causes osteonecrosis and osteonecrosis of the jaw, a serious and disfiguring medical condition.

JURISDICTION AND VENUE

1. The jurisdiction of this Court over the subject matter of this action is predicated on 28 USC Section 1332. The amount in controversy exceeds \$75,000.00, exclusive of interest and costs. Venue in this Court is proper pursuant to 28 U.S.C. §1391 in that substantial part of the events or omissions giving rise to the claims asserted herein

1 occurred in this District, and Defendant is subject to personal jurisdiction in this District.

2 **GENERAL ALLEGATIONS**

3 2. This action is an action for damages brought by Plaintiffs' who suffered
4 injury as a result of being prescribed and ingesting Fosamax. Fosamax is a prescription
5 drug which was tested, studied, researched, evaluated, endorsed, designed, formulated,
6 compounded, manufactured, produced, processed, assembled, inspected, distributed,
7 marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise
8 placed in the stream of interstate commerce by Defendant.

9 3. The injuries and damages to Plaintiffs' were caused by the wrongful acts,
10 omissions, and fraudulent misrepresentations of Defendant.

11 4. At all times relevant, Defendant was engaged in the business of, or was
12 successor in interest to, entities engaged in the business of research, licensing, designing,
13 formulating, compounding, testing, manufacturing, producing, processing, assembling,
14 inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for
15 sale or selling Fosamax for the use and ingestion by Plaintiffs'.

16 5. At all times relevant, Defendant was authorized to do business within the
17 state of California.

18 6. At all times relevant, the officers and directors of the Defendant named
19 herein participated in, authorized and directed the production and promotion of Fosamax
20 when they knew, or with the exercise of reasonable care should have known, of the
21 hazards and dangerous propensities of the product and thereby actively participated in the
22 tortious conduct which resulted in the injuries suffered by Plaintiffs'.

23 7. Plaintiffs file this lawsuit within the applicable limitations period of first
24 suspecting that Fosamax was the cause of any appreciable harm sustained by Plaintiffs.
25 Plaintiffs could not, by the exercise or reasonable diligence, have discovered the wrongful
26 cause of Plaintiffs' injuries at an earlier time because the injuries were caused without
27 perceptible trauma or harm, and when Plaintiffs' injuries were discovered, their cause was
28 unknown to Plaintiffs.

8. Additionally, Plaintiffs were prevented from discovering this information sooner because Defendant misrepresented and continues to misrepresent to the public and to the medical profession that Fosamax is safe and free from serious side effects, and Defendant have fraudulently concealed facts and information that could have led Plaintiffs' to discover a potential cause of action.

THE PARTIES

Plaintiff

9. Plaintiff, MARIA COMBS, is a citizen of the United States and a resident of Palmdale, California. She took Fosamax manufactured, supplied and/or marketed by Defendant, and was injured as a result.

10. Plaintiff, ARDELL SMITH, is a citizen of the United States and a resident of Lancaster, California . She took Fosamax manufactured, supplied and/or marketed by Defendant, and was injured as a result.

Defendant

11. Defendant MERCK & CO., INC. was and is an American pharmaceutical company, incorporated under the laws of the state of New Jersey, whose principal place of business is One Merck Drive, P.O. Box 103, Whitehouse Station, New Jersey. On information and belief, said entity does business in California, and at all times relevant it developed, manufactured, and sold Fosamax in interstate commerce and in California.

12. At all times relevant, Defendant did test, study, research, evaluate, endorse, design, formulate, compound, manufacture, produce, process, assemble, inspect, distribute, market, label, promote, warn, package, advertise for sale, prescribe, sell and distribute, or otherwise place in the stream of interstate commerce, Fosamax, which was ingested by Plaintiffs.

FACTUAL BACKGROUND

13. The compound alendronate is marketed by Defendant as Fosamax. Fosamax is a member of the bisphosphonate class of drugs. The Food and Drug Administration approved Fosamax on September 29, 1995 for the treatment of post-

1 menopausal osteoporosis and Paget's disease. Subsequent to FDA approval, Fosamax
2 was widely promoted, advertised and marketed by Defendant as a safe and effective
3 medication.

4 14. Osteoporosis is a thinning and weakening of bones through the natural
5 process of bone remodeling. In bone remodeling, osteoclasts (bone-eroding cells) break
6 down bone through resorption, and osteoblasts (bone-building cells) build bone back up
7 again through bone formation. These processes usually are in balance and a stable bone
8 mass is maintained. Osteoporosis occurs when the formation of new bone does not keep
9 up with bone destruction and bones become weak and fragile. As a bisphosphonate,
10 Fosamax is designed to suppress bone resorption by inactivating bone-eroding osteoclast
11 cells thus preserving bone density.

12 15. As osteoporosis is a common and widespread disease, the market for
13 osteoporosis treatments is enormous. Nearly 200 million women worldwide suffer from
14 osteoporosis – approximately one-third of women aged 60-70 and two-thirds of women
15 over the age of 80. In the United States, approximately 44 million Americans are at risk
16 for developing osteoporosis (approximately 55% of Americans 50 years old or older) and
17 current estimates are that 10 million Americans currently have the disease with 34 million
18 estimated to have low bone mass, putting them at great risk for the disease.¹

19 16. Today, the "global osteoporosis market exceeds \$6 billion in annual sales,
20 and with a rapidly graying population, it's growing 25% a year."² Defendant commands a
21 large share of the osteoporosis treatment market with Fosamax, the second best selling
22 drug for the company with annual sales in excess of \$3.2 billion dollars.

23 17. According to IMS Health, more than 22 million prescriptions were written
24

25 ¹ Statistics are from National Osteoporosis Foundation, available online at:
26 <http://www.nof.org/osteoporosis/diseasefacts.htm>.

27 ² See Business Week Online, "Rebuilding Amgen's Bones; A mass-market osteoporosis
28 drug could help reassure antsy investors," May 15, 2006, available online at:
http://www.businessweek.com/magazine/content/06_20/b3984089.htm?chan=search.

1 for Fosamax in 2005, up 2% from 2004.³ Defendant's Fosamax continues to make IMS
2 Health's "Leading 20 Products by Total U.S. Dispensed Prescriptions" and it is the
3 world's best-selling osteoporosis treatment. Defendant launched an aggressive
4 advertising campaign for Fosamax, which paid off causing physician visits for
5 osteoporosis to nearly double.⁴ Capitalizing on the increased attention to osteoporosis, in
6 2005 Defendant obtained approval for an additional drug in the Fosamax family, Fosamax
7 Plus D, which claims to have the additional value of providing a "minimum vitamin D
8 intake consistent with the recommended guidelines..."⁵

9 18. Bisphosphonates are divided into two classes of agents based on their
10 chemical structure and molecular mechanism of action – simple bisphosphonates where
11 there is no nitrogen functionality in their structure, and more potent nitrogen-containing
12 bisphosphonates. Nitrogenous bisphosphonates are 10-100 times more potent at
13 inhibiting bone resorption than simple bisphosphonates.

14 19. Fosamax is a nitrogenous bisphosphonate. It is not metabolized in humans.
15 The presence of a primary nitrogen atom in the molecule, and the non-metabolizing
16 nature of the compound, results in Fosamax having a terminal half-life of more than ten
17 years, which can result in a massive cumulative dose over the multi-year dosing cycle.

18 20. In the 1990s and 2000s, medical articles and studies were published
19 reporting the occurrence of osteonecrosis (bone death) and osteonecrosis of the jaw
20

21 ³ See IMS Health's "Leading 20 Products by Total U.S. Dispensed Prescriptions"
22 available online at:
23 http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_73914140_77250364,00.html.

24 ⁴ See Consumer Reports, "Free rein for drug ads? A slowdown in FDA review has left
25 consumers more vulnerable to misleading messages", February 2003, available online at:
26 [http://www.consumerreports.org/cro/health-fitness/drugs-supplements/drug-ads-203/overview/in
dex.htm](http://www.consumerreports.org/cro/health-fitness/drugs-supplements/drug-ads-203/overview/index.htm).

27 ⁵ See Merck and Company, Inc.'s 2005 Annual Report, Financial Section, p. 23, available
28 online at:
http://www.merck.com/finance/annualreport/ar2005/pdf/Merck_2005_Financial_Section.pdf.

1 (“ONJ”) when nitrogenous bisphosphonates were used in the treatment of cancer.

2 Defendant knew or should have known that Fosamax, as a nitrogenous bisphosphonate,
3 shared the mechanism of action and the adverse event profiles with similar drugs within
4 the nitrogenous subclass.

5 21. More specifically, Defendant knew or should have known that the
6 osteoclast-inhibiting effect of Fosamax leads to cessation of bone remodeling and bone
7 turnover, and induces cumulative ischemic changes to the human mandible (lower jaw)
8 and maxilla (upper jaw).

9 22. Defendant knew or should have known that these properties compromise
10 the vascular supply to the area, which reduces the ability of a minor injury or disease to
11 heal, which, in turn, can lead to osteonecrosis and osteomyelitis (bone marrow
12 inflammation).

13 23. ONJ is a serious medical condition that can result in significant disability
14 such as irreversible joint collapse in the jaw. Bone death as in ONJ is typically not
15 reversible, and consequently physicians are limited to easing patient’s pain and preventing
16 the necrosis from spreading.

17 24. After Defendant began selling Fosamax, reports of osteonecrosis, ONJ, and
18 other dental complications among its users began to surface. The early evidence
19 indicated that Fosamax shared the class effects of all nitrogenous bisphosphonates, yet
20 Defendant declined to conduct further study of the risk of osteonecrosis and ONJ in
21 Fosamax users. Rather than evaluating and verifying the safety of Fosamax with respect
22 to ONJ, Defendant sought to broaden the uses of Fosamax, including expanding approval
23 to Fosamax D, and sought to extend the exclusivity of the patent for Fosamax through
24 2018.

25 25. Since the launch of Fosamax in 1995, the Food and Drug Administration
26 (“FDA”) has received a significant number of reports of osteonecrosis and ONJ among
27 users of nitrogenous bisphosphonates in general, and Fosamax specifically. In 2004, the
28 FDA reported the results of their review of the FDA adverse events database for

1 bisphosphonates and concluded that the risk of osteonecrosis and ONJ was not limited to
2 intravenous nitrogenous bisphosphonates used in the treatment of cancer, but also to
3 Fosamax, an oral medication which shares the same mechanism of action as intravenous
4 bisphosphonates. The FDA concluded that osteonecrosis was a class effect based on the
5 reported cases involving Fosamax.

6 26. Citing a continuing safety concern for Fosamax and intravenous
7 bisphosphonates, the FDA recommended and stated that Fosamax should include a
8 warning on the label to alert unsuspecting physicians and consumers of the risk of
9 osteonecrosis. Defendant has ignored the FDA's recommendation and refused to include
10 any type of warning for osteonecrosis on its label or otherwise to this day. Physicians
11 continue to prescribe Fosamax without knowledge of the serious risk of osteonecrosis,
12 and consumers continue to take the medication believing there is no such risk. Indeed,
13 Defendant continues to defend Fosamax and downplay unfavorable findings.

14 27. At the time Plaintiffs and other Fosamax consumers took the drug, there
15 were other safer alternative treatments for their osteoporosis condition.

16 28. Defendant knew of the significant risk of osteonecrosis, and specifically
17 ONJ, but did not adequately and sufficiently warn physicians and consumers, including
18 Plaintiffs, of the risks.

19 29. As a direct result, Plaintiffs were prescribed Fosamax by their physicians,
20 and ingested Fosamax as prescribed and in a foreseeable manner for a long period of time
21 without knowledge of its dangerous side effects. Plaintiffs have suffered serious injury
22 from the ingestion of Fosamax, and requires and will require in the future ongoing
23 medical care and treatment.

24 30. As a direct result, Plaintiffs suffered severe mental and physical pain and
25 suffering and has sustained permanent injuries and emotional distress.

26 31. As a direct result, Plaintiffs sustained economic loss, including loss of
27 earnings and diminution or loss of earning capacity.

28 32. If Plaintiffs had known the risks and dangers associated with Fosamax®,

1 Plaintiffs would not have taken Fosamax and consequentially would not have been
2 subject to its serious side effects.

3 33. As a result of defendant's actions, Plaintiffs and their prescribing physicians
4 were unaware, and could not have reasonably known or have learned through reasonable
5 diligence, that Plaintiffs had been exposed to the risks identified in this complaint, and
6 that those risks were the direct and proximate result of Defendant's acts, omissions, and
7 misrepresentations.

8 **FIRST CLAIM FOR RELIEF**

9 **STRICT LIABILITY - FAILURE TO WARN**

10 34. Plaintiffs incorporate by reference to all preceding paragraphs as if fully set
11 forth herein.

12 35. Defendant is manufacturer and/or supplier of Fosamax.

13 36. The Fosamax manufactured and/or supplied by Defendant was and is
14 unaccompanied by proper warnings regarding all possible adverse side effects associated
15 with the use of Fosamax and the comparative severity and duration of such adverse
16 effects; the warnings given did not accurately reflect the symptoms, scope or severity of
17 the side effects.

18 37. Defendant failed to perform adequate testing in that adequate testing would
19 have shown that Fosamax possessed serious potential side effects with respect to which
20 full and proper warnings accurately and fully reflecting symptoms, scope and severity
21 should have been made, with respect to the use of this drug.

22 38. The Fosamax manufactured and/or supplied by Defendant was defective
23 due to inadequate post-marketing warning or instruction because, after the manufacturer
24 knew or should have known of the risk of injury from Fosamax, it failed to provide
25 adequate warnings to users or consumers of the product and continued to aggressively
26 promote the product.

27 39. As the producing cause and legal result of the defective condition of
28 Fosamax as manufactured and/or supplied by Defendant, and as a direct and legal result

1 of the negligence, carelessness, other wrongdoing and action(s) of Defendant described
2 herein:

3 (a) Plaintiffs have been injured in health, strength and activity and
4 suffered injuries to body and mind, the exact nature and extent of which are not known at
5 this time;

6 (b) Plaintiffs sustained economic loss, including loss of earnings and
7 diminution or loss of earning capacity, the exact amount of which is presently unknown;

8 (c) Plaintiffs require reasonable and necessary health care, attention and
9 services and did incur medical, health, incidental and related expenses. Plaintiffs' are
10 informed and believes and thereon alleges said plaintiffs' may in the future be required to
11 obtain medical and/or hospital care, attention, and services in an amount as yet
12 unascertained.

13 **SECOND CLAIM FOR RELIEF**

14 **NEGLIGENCE**

15 40. Plaintiffs incorporate by reference all preceding paragraphs as if fully set
16 forth herein.

17 41. Defendant had a duty to exercise reasonable care in the manufacture, sale
18 and/or distribution of Fosamax into the stream of commerce, including a duty to assure
19 that the product did not cause users to suffer from unreasonable, dangerous side effects.

20 42. Defendant failed to exercise ordinary care in the manufacture, design,
21 formulation, distribution, production, processing, assembly, inspection, marketing,
22 labeling, packaging, preparation for use and sale of Fosamax into interstate commerce in
23 that Defendant knew or should have known that the product Fosamax created a high risk
24 of unreasonable, dangerous side effects, some of which, e.g. osteonecrosis and ONJ, can
25 cause extraordinary suffering.

26 43. Defendant was negligent in the design, manufacture, testing, advertising,
27 warning, marketing, and sale of Fosamax in that they:

28 (a) Failed to use due care in designing and manufacturing Fosamax so as

1 to avoid the above risks to individuals when Fosamax was being used to treat
2 osteoporosis and Paget's disease;

3 (b) Failed to accompany their product with proper warnings regarding
4 all possible adverse side effects associated with the use of Fosamax and the comparative
5 severity and duration of such adverse effects, the warnings did not accurately reflect the
6 symptoms, scope or severity of the side effects;

7 (c) Failed to conduct adequate pre-clinical and clinical testing and
8 post-marketing surveillance to determine the safety of Fosamax;

9 (d) Failed to provide adequate instruction and warning to medical care
10 providers for the appropriate use of Fosamax;

11 (e) Were otherwise careless or negligent.

12 44. Despite the fact that Defendant knew or should have known that Fosamax
13 caused unreasonable, dangerous side effects which many users would be unable to
14 remedy by any means, Defendant continued to market Fosamax when there were safer
15 alternative methods of treatment.

16 45. Defendant knew or should have known that consumers such as Plaintiffs
17 would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care
18 as described above.

19 46. Defendant's negligence was a proximate cause of Plaintiffs' injuries, harm
20 and economic loss which she suffered and will continue to suffer as previously described.

21 **THIRD CLAIM FOR RELIEF**

22 **FOR BREACH OF IMPLIED WARRANTY**

23 47. Plaintiffs incorporate by reference all preceding paragraphs as if fully set
24 forth herein.

25 48. At all times relevant herein, Defendant impliedly warranted to members of
26 the public and health care providers that the product was of merchantable quality and safe
27 and fit for use as a treatment for osteoporosis and Paget's disease.

28 49. Plaintiffs were and are unskilled in the research, design and manufacture of

1 Fosamax and reasonably relied entirely on the skill, judgment and implied warranty of
2 Defendant in using the product.

3 50. At all times that Defendant marketed, sold and/or distributed Fosamax for
4 use by Plaintiffs, Defendant had actual or constructive knowledge of the particular
5 purpose for which this drug was to be used by Plaintiffs.

6 51. At all times that Defendant marketed, sold and/or distributed Fosamax
7 Defendant knew or had reason to know that Plaintiffs were relying and in fact did rely on
8 Defendant's implied warranties.

9 52. Plaintiffs and their physicians reasonably relied upon the skill and judgment
10 of Defendant as to whether Fosamax was of merchantable quality and safe and fit for its
11 intended use.

12 53. Contrary to such implied warranty, Fosamax was not of merchantable
13 quality or safe or fit for its intended use, because the product was and is unreasonably
14 dangerous and unfit for the ordinary purposes for which it was used as described above
15 and Defendant has breached its implied warranty.

16 54. As a direct and legal result of the breach of implied warranty, Plaintiffs
17 suffered and will continue to suffer damages, injury, harm and economic loss as alleged
18 herein.

19 **FOURTH CLAIM FOR RELIEF**

20 **FOR BREACH OF EXPRESS WARRANTY**

21 55. Plaintiffs incorporate by reference all preceding paragraphs as if fully set
22 forth herein.

23 56. At all times relevant, Defendant expressly represented and warranted to
24 Plaintiffs and Plaintiffs' agents and physicians, by and through statements made by
25 Defendant or its authorized agents or sales representatives, orally and in publications,
26 package inserts and other written materials intended for physicians, medical patients and
27 the general public, that Fosamax was safe, effective, fit and proper for its intended use.
28 In reliance upon said warranties, Plaintiffs purchased said product.

1 57. Plaintiffs, along with the general public, relied directly and indirectly, upon
2 said express warranties made by Defendant, in connection with the use of Fosamax. Said
3 express warranties were part of the sale of the product, in that Defendant warranted the
4 safeness of the product.

5 58. Fosamax does not conform to these express representations because
6 Fosamax is not safe and has high levels of serious side effects, including disfiguring and
7 life threatening side effects.

8 59. As a direct and legal result of the breach of said warranties, Plaintiffs suffer
9 and will continue to suffer damages, injury, harm and economic loss as alleged herein.

10 **FIFTH CLAIM FOR RELIEF**

11 **DECEIT BY CONCEALMENT**

12 60. Plaintiffs incorporate by reference all preceding paragraphs as if fully set
13 forth herein.

14 61. Defendant, from the time that Fosamax was first tested, studied, researched,
15 evaluated, endorsed, manufactured, marketed and distributed, and up to the present,
16 willfully deceived Plaintiffs by concealing from Plaintiffs, Plaintiffs' physicians and the
17 general public, the true facts concerning Fosamax, which Defendant had a duty to
18 disclose.

19 62. Defendant represented through its labeling, advertising, marketing
20 materials, detail persons, seminar presentations, publications, notice letters, and
21 regulatory submissions that Fosamax was safe and willfully withheld and concealed
22 information about the substantial risks of using Fosamax.

23 63. Defendant represented that Fosamax was safer than other alternative
24 medications and willfully concealed information which demonstrated that Fosamax was
25 not safer than alternatives available on the market.

26 64. At all times relevant herein, Defendant conducted a sales and marketing
27 campaign to promote the sale of Fosamax and willfully deceive Plaintiffs, Plaintiffs'
28 physicians and the general public as to the health risks and consequences of the use of

1 Fosamax. Defendant was aware of the foregoing, and that Fosamax was not safe, fit and
2 effective for human consumption, the use of Fosamax is hazardous to health, and
3 Fosamax has a serious propensity to cause serious injuries to users, including but not
4 limited to the injuries suffered by Plaintiffs as delineated herein.

5 65. Defendant intentionally concealed and suppressed the true facts concerning
6 Fosamax with the intent to defraud Plaintiffs, in that Defendant knew that Plaintiffs'
7 physicians would not prescribe Fosamax, and Plaintiffs' would not have used Fosamax, if
8 they were aware of the true facts concerning the dangers of Fosamax.

9 66. As a result of the foregoing fraudulent and deceitful conduct by the
10 Defendant, Plaintiffs suffered injuries and damages as alleged herein.

11 **SIXTH CLAIM FOR RELIEF**

12 **NEGLIGENT MISREPRESENTATION**

13 67. Plaintiffs incorporate by reference all preceding paragraphs as if fully set
14 forth herein.

15 68. From the time that Fosamax was first tested, studied, researched, evaluated,
16 endorsed, manufactured, marketed and distributed, and up to the present, Defendant made
17 false misrepresentations, as previously set forth herein, to Plaintiffs, Plaintiffs' physicians
18 and the general public, including but not limited to the misrepresentation that Fosamax
19 was safe, fit and effective for human consumption. At all times relevant, Defendant
20 conducted a sales and marketing campaign to promote the sale of Fosamax and willfully
21 deceive Plaintiffs, Plaintiffs' physicians and the general public as to the health risks and
22 consequences of the use of the product.

23 69. Defendant made the foregoing representations without any reasonable
24 ground for believing them to be true. These representations were made directly by
25 Defendant, by sales representatives and other authorized agents of said Defendant, and in
26 publications and other written materials directed to physicians, medical patients and the
27 public, with the intention of inducing reliance and the prescription, purchase and use of
28 Fosamax.

1 70. The foregoing representations by the Defendant were in fact false, in that
2 Fosamax was not safe, fit and effective for human consumption, the use of Fosamax is
3 hazardous to health, and Fosamax has a serious propensity to cause serious injuries to
4 users, including but not limited to the injuries suffered by Plaintiffs as delineated herein.

5 71. The foregoing representations by Defendant were made with the intention
6 of inducing reliance and the prescription, purchase and use of Fosamax.

7 72. In reliance on the misrepresentations by Defendant, Plaintiffs were induced
8 to purchase and use Fosamax. If Plaintiffs' had known of the true facts and the facts
9 concealed by the Defendant, Plaintiffs would not have used Fosamax. The reliance of
10 Plaintiffs upon Defendant's misrepresentations was justified because such
11 misrepresentations were made and conducted by individuals and entities that were in a
12 position to know the true facts.

13 73. As a result of the foregoing negligent misrepresentations by Defendant,
14 Plaintiffs suffered injuries and damages as alleged herein.

15 **PUNITIVE DAMAGES ALLEGATIONS**

16 **(As to the First, Second, Fifth, and Sixth Claims for Relief, only)**

17 74. Plaintiffs incorporate by reference all preceding paragraphs as if fully set
18 forth herein.

19 75. The acts, conduct, and omissions of Defendant, as alleged throughout this
20 Complaint were willful and malicious and were done with a conscious disregard for the
21 rights of Plaintiffs and other users of the Defendant's product and for the primary purpose
22 of increasing Defendant's profits from the sale and distribution of Fosamax. Defendant's
23 outrageous and unconscionable conduct warrants an award of exemplary and punitive
24 damages against Defendant in an amount appropriate to punish and make an example of
25 Defendant.

26 76. Prior to the manufacturing, sale and distribution of Fosamax, Defendant
27 knew that said medication was in a defective condition as previously described herein and
28 knew that those who were prescribed the medication would experience and did

1 experience severe physical, mental, and emotional injuries. Further, Defendant, through
2 its officers, directors, managers, and agents, had knowledge that the medication presented
3 a substantial and unreasonable risk at harm to the public, including Plaintiffs and as such,
4 said consumers of said drugs were unreasonably subjected to risk of injury or death from
5 the consumption of said product.

6 77. Despite such knowledge, Defendant, acting through their officers, directors
7 and managing agents for the purpose of enhancing Defendant's profits, knowingly and
8 deliberately failed to remedy the known defects in said medication and failed to warn the
9 public, including Plaintiffs, of the extreme risk of injury occasioned by said defects
10 inherent in Fosamax. Defendant and its individual agents, officers, and directors
11 intentionally proceeded with the manufacturing, sale, and distribution and marketing of
12 Fosamax knowing persons would be exposed to serious danger in order to advance
13 Defendant's own pecuniary interest and monetary profits.

14 78. Defendant's conduct was despicable, and so contemptible that it would be
15 looked down upon and despised by ordinary decent people, and was carried on by
16 Defendant with willful and conscious disregard for the safety of Plaintiffs' entitling
17 Plaintiffs to exemplary damages.

18 **WHEREFORE**, Plaintiffs pray for judgment against Defendant as follows, as
19 appropriate to each cause of action:

20 1. General damages in an amount that will conform to proof at time of trial;

21 2. Special damages in an amount within the jurisdiction of this Court and
22 according to proof at the time of trial;

23 3. Loss of earnings and impaired earning capacity according to proof at the
24 time of trial;

25 4. Medical expenses, past and future, according to proof at the time of trial;

26 5. For past and future mental and emotional distress, according to proof;

27 6. For punitive or exemplary damages according to proof on the First, Second,
28 Fifth, and Sixth Causes of Action;

7. Attorney's fees;
8. For costs of suit incurred herein;
9. For pre-judgment interest as provided by law; and
10. For such other and further relief as the Court may deem just and proper.

Dated: April 30, 2008

GANCEDO & NIEVES
A Limited Liability Partnership

By


HECTOR G. GANCEDO
TINA B. NIEVES

Attorneys for Plaintiffs

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury.

Dated: April 30, 2008

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HECTOR G. GANCEDO
TINA B. NIEVES

Attorneys for Plaintiffs